REMARKS

Claims 1-2 and 5-19 are pending in this application. Claims 1-2 and 5-19 were rejected under 35 U.S.C. § 103.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejection under 35 U.S.C. § 103

Claims 1-2 and 5-19 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Levy *et al.* (U.S. Pat. No. 5,798,349, "Levy"). Applicants respectfully traverse this rejection.

The claimed invention is directed to a method of treating an occult choroidal neovascular (CNV) lesion by providing photodynamic therapy (PDT) to a subject assessed as having a small lesion and/or poor visual acuity. Specifically, subjects to be treated have a small lesion with a size less than about 4-5 disc areas and/or poor visual acuity of less than about 65 letters prior to treatment.

Levy describes the use of PDT for treating unwanted CNV, including that which occurs in age-related macular degeneration (AMD). As acknowledged by the Examiner, Levy does not "specifically disclose the subject's lesion size or visual acuity of subject at baseline to be less than 65 letters." Office Action, page 2. In fact, Levy is silent with regard to visual acuity of the subject. Levy is also silent with regard to lesion size before PDT treatment.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in Levy itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teaching. Second, there must be a reasonable expectation of success. Finally, Levy must teach or suggest all the claim limitations. The teaching or suggestion of the reasonable expectation of success must be found in Levy, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented herein, Applicants respectfully submit that a *prima facie* case of obviousness has not been established over Levy.

The Examiner asserts that it would have been obvious "to determine by routine experimentation what type CNV lesions size would best benefit from Levy's method, or even characterize what type of patient population, based on their visual acuity, would best benefit from Levy's methods." The Examiner further states that the Office "does not argue that it would have been obvious for one of ordinary skill in the art to varying every parameter of the therapy taught by Levy in order to optimize the effectiveness of the therapy. Rather, those parameters that are clearly established by Levy and the art to affected the clinical result." Office Action, pages 3 and 4, emphasis added. In support, the Examiner cites tables 2-7 of Levy and states that "Levy provides for effectiveness of PDT for treating different types of CNV. Levy further determines the size and type of lesions best treated by his methods and identifies potential candidates." Office Action, page 4.

Applicants respectfully disagree with this interpretation of the teachings of Levy and respectfully point out that Levy does not describe or suggest determining visual acuity of the subject or lesion size prior to PDT. For example, tables 2-6 of Levy present angiography and histology results of lesions after PDT treatment on experimentally induced CNV and on normal choroid tissue. None of the information in these tables describes the size and type of lesions to best be treated or in any way identifies potential candidates for treatment.

The Examiner states that Levy provides ample evidence for effectiveness of PDT "in treating different type of lesion by their histological grading (see col 13, lines 1-67)," that Table 7 provides "adequate guidance as to the type of lesions that are treated by Levy's methods," and then concludes that "determining the optimal lesion size that would benefit from Levy's methodology would have been obvious." Office Action, page 4. Applicants respectfully point out that column 13 and Table 7 of Levy describe the histology of lesions after PDT was performed in normal retina/choroid. Thus, this citation in Levy does not describe or suggest that the size of a CNV lesion prior to PDT is a parameter or variable to be considered before treatment of CNV, much less before PDT treatment of occult CNV. Accordingly, the Examiner's reasons for this rejection are not supported the teachings of Levy. Contrary to the Examiner's position, the skilled artisan would not find suggestion or motivation in Levy to use visual acuity or lesion size as a parameter or variable to be considered prior to PDT treatment of CNV.

Applicants also submit that Levy provides the skilled artisan no motivation to modify the teachings therein to arrive at the claimed invention, *i.e.*, to use the particular visual acuity score and/or particular lesion size prior to treating occult CNV with PDT.

The Examiner points to Levy's discussion of treating age-related macular degeneration as a disclosure which includes treating occult CNV. Applicants respectfully disagree that the reference necessarily refers to occult CNV. As described in the specification,[1] CNV lesions associated with AMD can be comprised of differing lesion types including occult CNV, classic CNV, combinations of both occult and classic CNV, and lesions of neither occult or classic CNV. Levy is silent with regard to the type of CNV lesions studied. Applicants respectfully point out that a recommendation from the Treatment of Age-related Macular Degeneration with Photodynamic Therapy (TAP) study group was that of PDT "for treatment of patients with predominantly classic CNV from AMD."[2] This study found no major differences between the PDT test and placebo groups in outcomes for occult CNV. Thus, there is no motivation in the art for the skilled artisan to

[1] See Specification, for example, pages 1-4.
[2] See, *Arch. Ophthalmol.* 117:1329-1345 (1999), of record, for example at pages 1329 and 1337.

modify the teachings of Levy to arrive at the claimed invention, *i.e.*, the use of PDT for the treatment of occult CNV.

In support of the rejection, the Examiner states that "the question of whether a particular parameter can be optimized or not is addressed in *In re Antoine*[3]" and concludes that "maximizing the efficacy of [Levy's] therapy based on such parameters would have been a matter of routine experimentation." Office Action, page 4.

However, according to the M.P.E.P. §2144.05 IIB and *In re Antonie*, a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In *In re Antonie*, the parameter optimized was not recognized in the art to be a result-effective variable and the invention was found not obvious. The Court in *In re Antonie* also states that "[j]ust as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention as a whole, and not some part of it, which must be obvious under 35 U.S.C. 103." Emphasis added.

Again, Levy does not teach or suggest the claimed lesion parameters prior to treatment of occult CNV. Given Levy's silence with regard to the claimed parameters, Applicants respectfully submit that variables such as small lesion and/or poor visual acuity in occult CNV lesions were not recognized as "result-effective variables" prior to the instant invention. Contrary to the Examiner's assertion, the claimed parameters are not clearly established by Levy or the art to affect the clinical result. Thus, the claimed invention is not obvious in view of Levy.

Given the state of the art and Levy's silence with regard to treating the particular lesions as claimed, Applicants also respectfully submit that one of skill in the art would have no expectation of success for the claimed invention.

[3] *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

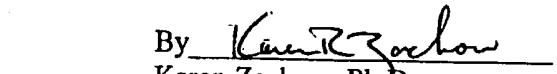
CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 273012012500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 28, 2004

Respectfully submitted,

By 

Karen Zachow, Ph.D.
Registration No.: 46,332
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-5191